

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant : Kristin Feeley et al. Art Unit : 3763
Serial No. : 10/786,021 Examiner : Catherine Williams
Filed : February 26, 2004 Conf. No. : 2923
Title : ANTIMICROBIAL AGENT DELIVERY SYSTEM

Mail Stop Appeal Brief - Patents

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

CORRECTED BRIEF ON APPEAL

Applicants previously authorized charging the Appeal Brief fee of \$510 and application of any other charges or credits to Deposit Account No. 06-1050, referencing Attorney Docket No. 01194-514001.

(1) Real Party in Interest

The real party in interest in the above application is BOSTON SCIENTIFIC SCIMED, INC., a corporation of Minnesota, having a place of business at One Scimed Place, Maple Grove, MN 55311-1566.

(2) Related Appeals and Interferences

The Appellant is not aware of any appeals or interferences related to the above-identified patent application.

(3) Status of Claims

Claims 1-6 and 9-20 are pending, with claims 6, 9-11, 13 and 20 being withdrawn from consideration.

This is an appeal from the rejections of claims 1-5, 12 and 14-19 provided by the Examiner in the Final Office Action mailed August 1, 2007. Claims 1-5, 12 and 14-19 have been twice rejected and are presented for appeal.

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(4) Status of Amendments

All amendments have been entered.

(5) Summary of Claimed Subject Matter

This paragraph corresponds to a summary of the subject matter covered by independent claim 1. In one aspect, the invention relates to an antimicrobial agent delivery system.

(Application as filed, p. 3, lines 8-9; p. 4, line 30-p. 5, line 22 and Figs. 1A-1C.) The system includes an antimicrobial agent-bearing intervention device and a hub coupled to the intervention device. (*Id.*, p. 3, lines 8-17; p. 4, line 30-p. 5, line 17 and Figs. 1A-1C.) The system also includes a delivery tube having a perforated longitudinal partition with a hub opening. (*Id.*, p. 3, lines 8-17; p. 4, line 30-p. 5, line 22 and Figs. 1A-1C.) The delivery system is configured so that longitudinal movement of the hub ejects the intervention device from the delivery tube. (*Id.*, p. 3, lines 8-17; p. 5, lines 18-22 and Figs. 1A-1C.)

This paragraph corresponds to a summary of the subject matter covered by independent claim 18. In another aspect, the invention relates to a method of fabricating an antimicrobial agent delivery system. (*Id.*, p. 3, lines 19-20; p. 7, line 23-p. 8, line 3 and Fig. 8.) The method includes coupling a hub to an antimicrobial agent-bearing intervention device, and forming a perforated longitudinal partition and a hub opening in a delivery tube. (*Id.*, p. 3, lines 20-22; p. 7, lines 24-26 and Fig. 8.) The method also includes disposing the intervention device within the delivery tube, the hub opening providing external access to the hub, wherein the system is configured so that longitudinal movement of the hub ejects the intervention device from the delivery tube. (*Id.*, p. 3, lines 22-23; p. 5, lines 18-22; p. 7, lines 26-28 and Fig. 8.)

Claims 1 and 18 are the only independent claims. These claims read as follows:

1. An antimicrobial agent delivery system comprising:
 - an antimicrobial agent-bearing intervention device;
 - a hub coupled to the intervention device; and
 - a delivery tube having a perforated longitudinal partition with a hub opening;

wherein the delivery system is configured so that longitudinal movement of the hub ejects the intervention device from the delivery tube.

18. A method of fabricating an antimicrobial agent delivery system comprising:
coupling a hub to an antimicrobial agent-bearing intervention device;
forming a perforated longitudinal partition and a hub opening in a delivery
tube; and
disposing the intervention device within the delivery tube, the hub opening
providing external access to the hub, wherein the system is configured so that
longitudinal movement of the hub ejects the intervention device from the delivery
tube.

(6) Grounds of Rejection to be Reviewed on Appeal

Claims 1-4, 12 and 18-19 were rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 3,595,230 ("Suyeoka") in view of U.S. Publication No. 2003/0175323 ("Utterberg") and in further view of U.S. Publication No. 2003/0212373 ("Hall").

Claim 5 was rejected under 35 U.S.C. § 103(a) as being unpatentable over Suyeoka in view of U.S. Patent No. 6,726,658 ("Hochman").

Claims 14-16 were rejected under 35 U.S.C. §103(a) as being unpatentable over Suyeoka in view of Utterberg in view of Hall, and further in view of U.S. Patent No. 5,419,766 ("Chang").

(7) Argument

For the purposes of this appeal only claims 1-5, 12 and 14-19 stand or fall together.

Claims 1 and 18 are the only independent claims and thus are representative of this group of claims.

**(a) Claims 1-4, 12 and 18-19 are patentable over Suyeoka
in view of Utterberg and in further view of Hall**

The Examiner rejected claims 1-4, 12, and 18-19 under 35 U.S.C. § 103(a) as being unpatentable over Suyeoka in view of Utterberg and in further view of Hall.

Claims 1-4, 12, and 18-19 cover systems that include an antimicrobial agent-bearing intervention device and a delivery tube having a perforated longitudinal partition with an opening.

Without conceding that Suyeoka could be properly construed as disclosing the other elements required by claims 1-4, 12 and 18-19, as admitted by the Examiner, Suyeoka does not disclose an antimicrobial agent-bearing intervention device. (Office Action mailed August 1, 2007, at 2.) Thus, Suyeoka does not disclose the systems covered by claims 1-4, 12, and 18-19. Contrary to the Examiner's assertion, however, there is no indication to modify Suyeoka to provide a system with an antimicrobial agent-bearing intervention device. Rather, Suyeoka discloses a catheter placement unit including a catheter shield with a catheter and a needle positioned within the catheter, where the shield has a longitudinal slot of varying width to lock the needle in place in the shield and allow freeing of the catheter from the shield and the needle. (See, e.g., Suyeoka, Abstract, col. 1, line 63-73, and Figs 1, 2, and 8.) The shield is provided to maintain the sterility of the catheter and needle assembly. (Id., col. 1, line 74- col. 2, line 4.) According to Sukyeoka, the "shield enables the assembled needle and catheter to be manipulated and handled without contamination". (Id., col. 3, lines 57-60.) Thus, after reading Suyeoka, it would not have been obvious to one skilled in the art to modify Suyeoka to incorporate an antimicrobial agent-bearing intervention device into his device. Accordingly, it would not have been obvious to one skilled in the art to modify Suyeoka based on the disclosure of Utterberg in the manner suggested by the Examiner.

Further, again without conceding that Suyeoka could be properly construed as disclosing the other elements required by claims 1-4, 12 and 18-19, as admitted by the Examiner, Suyeoka does not disclose a delivery tube having a perforated longitudinal partition with an opening. (Office Action mailed August 1, 2007, at 3.) Hence, for this reason also Suyeoka does not disclose the systems covered by these claims. In addition, contrary to the Examiner's position, there is no indication to modify Suyeoka to provide a system with a perforated longitudinal partition with an opening. Instead, Suyeoka discloses that, while his shield is flexible, it is also rigid. (See, e.g., Suyeoka, col. 1, lines 63-69 and Figs. 1 and 2). The shield includes a continuous slit with a large slot and a small slot. (Id., col. 3, lines 37-48 and Figs. 2 and 8.) The large slot can lock a needle thumb tag and thus immobilize the needle in the shield so that a catheter fin can be forced forward into the small slot in the shield to advance the catheter into the vein, after which the catheter can be released from the needle and remain in the vein. (See, e.g., id., col. 4, lines 11-42, col. 5, line 55-col. 6, line 12, and Figs. 1, 2, 7 and 8.) It is therefore

apparent that the shield is rigid so that it can sustain the force used to which it is subjected under these use conditions, and the slots of varying width are specifically arranged to allow for the intended use of the device. Thus, after reading Suyeoka, it would not have been obvious to one skilled in the art to modify Suyeoka to replace his continuous slit and slots with a perforated longitudinal partition with an opening. As a result, it would not have been obvious to one skilled in the art to modify Suyeoka based on the disclosure of Hall in the manner suggested by the Examiner. Even if it would have been obvious to one skilled in the art would to somehow modify Suyeoka based on the disclosure of Hall in the manner suggested by the Examiner, which Appellant does not concede would have happened because Suyeoka and Hall are each directed to such different devices, the result would not have been a device having a perforated longitudinal partition with an opening, at least because Hall does not disclose a perforated longitudinal partition. Rather, Hall discloses a flexible peel-away sheath with at least one weakened area (e.g., in the form of perforations) in a non-longitudinal pattern for a catheter that is not susceptible to kinking and that efficiently transfers torsional loads throughout the sheath. (See, e.g., Hall at Abstract, paragraphs [0006] and [0008].)

None of Suyeoka, Utterberg, or Hall, alone or in combination, discloses or renders obvious the subject matter covered by claims 1-4, 12 and 18-19. Appellant therefore requests reversal of the rejection of claims 1-4, 12, and 18-19.

(b) Claim 5 is patentable over Suyeoka in view of Hochman

The Examiner rejected claim 5 under 35 U.S.C. § 103(a) as being unpatentable over Suyeoka in view of Hochman. Claim 5 covers systems that include a delivery tube having a perforated longitudinal partition with an opening. As explained above, Suyeoka does not disclose or render obvious such a system. Hochman does not cure Suyeoka's deficiencies, at least because, like Suyeoka, Hochman does not disclose or render obvious a delivery tube having a perforated longitudinal partition with a hub opening. Thus, neither Suyeoka nor Hochman, alone or in combination, discloses or renders the subject matter covered by claim 5. Accordingly, Appellant requests reversal of this rejection.

(c) Claims 14-16 are patentable over Suyeoka Suyeoka in

view of Utterberg in view of Hall and further in view of Chang

The Examiner rejected claims 14-16 as being unpatentable under 35 U.S.C. §103(a) over Suyeoka in view of Utterberg in view of Hall and further in view of Chang. Claims 14-16 cover systems including a delivery tube having a perforated longitudinal partition with a hub opening. As explained above, none of Suyeoka, Utterberg, or Hall, alone or in combination, discloses or renders obvious such systems. Chang does not cure these deficiencies, at least because Chang also does not disclose or render obvious a delivery tube having a perforated longitudinal partition with a hub opening. Thus, none of Suyeoka, Utterberg, Hall, or Chang, alone or in combination, discloses or renders obvious the subject matter covered by claims 14-16. Appellant therefore requests reversal of this rejection.

(d) Claim 17 is patentable over Suyeoka

The Examiner also rejected claim 17 under 35 U.S.C. § 103(a) as being unpatentable over Suyeoka. Claim 17 covers systems that include an antimicrobial agent-bearing intervention and a delivery tube having a perforated longitudinal partition with a hub opening. As explained above, Suyeoka does not disclose or render obvious such subject matter. Thus, Appellant requests reversal of this rejection.

(e) Conclusion

Appellant submits, therefore, that claims 1-16, 18-27, and 29-34 are allowable over the cited art. Therefore, the Examiner erred in rejecting Appellant's claims, and the rejections should be reversed.

Applicants previously paid the \$510 Appeal Brief fee and believe that no further fee is due. Please apply any charges or credits to Deposit Account No. 06-1050, referencing Attorney Docket 01194-514001.

Respectfully submitted,

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Appendix of Claims

1. (Previously Presented) An antimicrobial agent delivery system comprising:
 - an antimicrobial agent-bearing intervention device;
 - a hub coupled to the intervention device; and
 - a delivery tube having a perforated longitudinal partition with a hub opening;
wherein the delivery system is configured so that longitudinal movement of the hub ejects the intervention device from the delivery tube.
2. (Original) The delivery system of claim 1, wherein the intervention device is a rod.
3. (Previously Presented) The delivery system of claim 1, wherein the hub opening provides external access to the hub, and the longitudinal partition guides the hub longitudinally.
4. (Previously Presented) The delivery system of claim 3, wherein the hub is disposed within the delivery tube, and the delivery system further comprises an extension arm coupled to the hub and extending through the hub opening.
5. (Original) The delivery system of claim 4, wherein the extension arm and the hub have a tapered connection point, and wherein the tapered connection point enables removal of the extension arm from the hub after ejection of the intervention device from the delivery tube.
6. (Withdrawn) The delivery system of claim 3, wherein the intervention device has a flex point and the hub is disposed outside the delivery tube.
- 7-8. (Cancelled).
9. (Withdrawn) The delivery system of claim 8, wherein the continuous slit is self-sealing.

10. (Withdrawn) The delivery system of claim 9, wherein the delivery tube comprises a low durometer thermoplastic polyurethane or polyethylene.
11. (Withdrawn) The delivery system of claim 1, wherein the delivery tube has a multiple lumen geometry defined by a first tube and a second tube, the intervention device being disposed within the first tube.
12. (Original) The delivery system of claim 1, wherein the hub has one or more apertures that enable fluid transfer through the hub when the intervention device is installed in a catheter.
13. (Withdrawn) The delivery system of claim 1, further including a plunger for pushing on the hub to eject the intervention device from the delivery tube.
14. (Original) The delivery system of claim 1, wherein an outer surface of the delivery tube includes at least one of a polyether block amide (PEBA), thermoplastic polyurethane (TPU), polyester elastomer, ionomer and thermoplastic vulcanizate to provide a relatively high surface texture.
15. (Original) The delivery system of claim 1, wherein the antimicrobial agent includes iodine, and wherein the delivery tube has an inner surface that is non-permeable to iodine.
16. (Original) The delivery system of claim 15, wherein the inner surface of the delivery tube is polyester or a similar material non-permeable to the particular antimicrobial agent.
17. (Original) The delivery system of claim 1, further including a valve coupled to an open end of the delivery tube.
18. (Previously Presented) A method of fabricating an antimicrobial agent delivery system comprising:
 - coupling a hub to an antimicrobial agent-bearing intervention device;

forming a perforated longitudinal partition and a hub opening in a delivery tube; and
disposing the intervention device within the delivery tube, the hub opening providing
external access to the hub, wherein the system is configured so that longitudinal movement of the
hub ejects the intervention device from the delivery tube.

19. (Original) The method of claim 18, further including:
 - coupling an external arm to the hub; and
 - disposing the hub within the delivery tube, the extension arm extending through the hub
opening.
20. (Withdrawn) The method of claim 18, wherein the intervention device has a flex point, the
method further including disposing the hub outside the delivery tube.

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Evidence Appendix

None

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Related Proceedings Appendix

None